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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/508,527 | 07/17/2000 | AKIKO ITAI | P19291 | 1282 |
| 7055 | 7590 | 10/14/2004 | EXAMINER | |
| GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191 | | | KIM, YOUNG J | |
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1637

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/508,527

Applicant(s)

ITAI, AKIKO

Examiner

Young J. Kim

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) . Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action responds the Amendment received on June 21, 2004.

Preliminary Remark

All rejections/objections hereto not reiterated should be considered withdrawn.

Claims 2 and 11-20 are canceled.

Claims 1 and 3-10 are pending and are under prosecution.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 1 and its dependent claims 3-10 under 35 U.S.C. 112, second paragraph as being indefinite for reciting the phrase, "high" is maintained for the reasons of record.

Applicants' arguments presented in the Amendment received on June 21, 2004 have been fully considered but they are not found persuasive.

Applicants contend that the specification, on page 23 discusses the selection of a template candidate protein by comparing scores and that the candidate with a high similarity score, "will be those which have the highest scores."

This argument is not found persuasive because the claim does not recite the limitation in which Applicants are relying on. MPEP 2106(II)(C) states that while it is appropriate to use the specification to determine what applicant intends a term to mean, a positive limitation from the specification cannot be read into a claim that does not impose that limitation.

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In other words, when one of ordinary skill in the art interprets the phrase, “choosing at least one template protein among the reference protein that has high similarity (not highest),” said one of ordinary skill in the art would not be able to readily determine the metes and bounds of which at least one template would be considered to have a high similarity versus low similarity.

The rejection of claim 7 under 35 U.S.C. 112, second paragraph as being indefinite for reciting the phrase, “matching by sliding one or more core segment sequences on the query sequence,” is maintained for the reasons of record.

Applicants’ arguments presented in the Amendment received on June 21, 2004 have been fully considered but they are not found persuasive.

Applicants contend that the specification, on page 18-19 discusses the matching of the candidate protein to the query protein to determine the best matching score and that the teaching of specification is, “clear, a segment sequence is slid down the query protein sequence until the best matching score is found... that the term, ‘sliding’ means simply that the segment sequence of the *candidate* protein is moved, or slid, down the query sequence until the segment sequence having the highest similarity is discovered.” (page 9, 1st paragraph, Response)

Initially, the cited passage of the specification discusses the sliding of a *candidate* protein sequence against the query protein. The instant claims do not recite the term, “candidate protein.” In addressing the argument, Examiner is assuming that the “candidate proteins” are the reference proteins being employed to compared against the query protein.

This argument is not found persuasive because the claim does not recite the limitation in which Applicants are relying on. MPEP 2106(II)(C) states that while it is appropriate to use the

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specification to determine what applicant intends a term to mean, a positive limitation from the specification cannot be read into a claim that does not impose that limitation.

In other words, claim 7 recites that the matching is conducted by, “sliding the two or more core segment sequences,” but fails to actively recite where the two or more core segment sequences are from. Further, there is insufficient antecedent basis for the limitation, “the two or more core segment sequences,” as the parent claim 1 only contains antecedent basis for a reference protein comprising “two or more segment sequences” not core segment sequences, thereby rendering the claim indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1 and 3-10 under 35 U.S.C. 102(b) as being anticipated by Eisenberg et al. (U.S. Patent No. 6,436,850, issued July 25, 1995), made in the Office Action mailed on October 1, 2003 is maintained for the reasons of record.

Applicants’ arguments presented in the Amendment received on June 21, 2004 have been fully considered but they are not found persuasive for the following reasons.

Applicants, on page 11, 2nd paragraph of the Response, contend that the rejection does not point to any teaching in Eisenberg (‘850 patent) which discusses the use of a “dynamic programming algorithm” in the disclosed method, but instead points to another teaching of

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unrelated patent, whose provisional application was filed more than two years after the issuance of Eisenberg et al. ('850 patent).

This assertion is wrong because the previous Office Action clearly states the following:

“The '850 patent discloses that all sequences in a database of target sequences are aligned with 3D structure profile **using a dynamic programming**, which allows insertions and deletions (or gaps) in the alignment,” (page 6, 2nd paragraph, Office Action) citing column 10 of the '850 patent.

Applicants' attention are drawn to this section of the '850 patent (Eisenberg et al.), wherein on column 10, beginning at line 61, the following is disclosed:

“In particular, all sequences in a database of target sequences are aligned with the 3D structure profile **using a dynamic programming** algorithm.”

Reading the entire disclosure on “3D Compatibility Searching,” on column 10, beginning at line 44, one of ordinary skill in the art would clearly understand that the use of dynamic programming algorithm is not another teaching of unrelated application, but employed by Eisenberg et al. of the cited U.S. Patent.

Additionally, with regard to Applicants remark about the inherent teaching being from an *unrelated patent application*, Applicants are advised that the U.S. Patent No. demonstrating the inherency (patent no. 6,512,981 B1) is also by the same artisan of the cited patent, that is Eisenberg et al. While not all patents by the same artisans are of the related inventions, '981 patent, relied on to demonstrate inherency, contrary to Applicants' assertion, is ***related*** and fully demonstrates the inherency of dynamic programming algorithm of the cited '850 patent.

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On column 10, beginning at line 61, the '850 patent disclose that dynamic programming algorithm is used. The specification further discusses that the, "[p]referred dynamic programming algorithms are taught in S.B. Needleman, C.D. Wunsch, *J. Mol. Biol.*, 48, 443-453 (1970) and T.F. Smith, M.S. Waterman, *Adv. Appl. Math*, 2, 482-489 (1981), and their use is discussed and demonstrated in M. Gribskov, A.D. McLachlan, and D. Eisenberg, *Proc. Natl. Acad. Sci. U.S.A.*, 84, 4355 (1987)..."

In the '981 patent which demonstrates the inherency of the dynamic programming, the specification discloses that the dynamic programming algorithms are taught by listing the same list of artisans disclosed by the '850 patent.

One of ordinary skill in the art, based on this disclosure, would clearly recognize that the dynamic programming algorithm employed by the '850 patent is the same algorithm discussed by the '981 patent.

Additionally, the filing date of the '981 patent antedates the filing date of the instant application, further demonstrating that dynamic programming algorithm has been known in the art.

Lastly, Applicants contend that to prove anticipation by inherency, the Examiner must show evidence which, "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference (page 11, 3rd paragraph, Response).

The dynamic programming algorithm employed in the '850 patent, the same algorithm described in further detail in the '981 patent is as follows:

"The "local" algorithm finds the highest-scoring aligned segment, allowing unpenalized-unaligned N- and C-termini both in the sequence and in the structure. The "global"

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alignment algorithm allows at most two unaligned termini without penalization, but requires that at least one N-terminus segment and one C-terminus segment of either the sequence or the structure be either aligned or penalized. The preferred embodiment uses a different variation, dubbed the "global-local" alignment. This algorithm does not penalize unmatched N- or C-termini segments in the probe sequence (local alignment), but does penalize any gaps in the target structure (global alignment). This variation produces more reliable scores than those obtained by the commonly used global or local algorithms. (column 9, lines 40-55).

Since Eisenberg et al. ('850 patent) employs a dynamic programming for the practice of their method, the programming of which involves segmentation analysis of N and C termini segment, the **inherency** of the dynamic programming **is** disclosed by Eisenberg et al. ('850 patent) as evidenced by Eisenberg et al. ('981 patent).

Therefore, Eisenberg et al. anticipate the invention for the above reasons.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

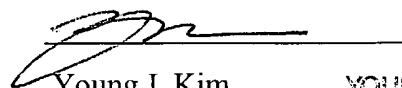
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Patent Examiner
Art Unit 1637
10/5/04

YOUNG J. KIM
PATENT EXAMINER



KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

10/6/04

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